

# PATENT COOPERATION TREATY

# PCT 10/561947

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference WP-042	<b>FOR FURTHER ACTION</b>	See item 4 below
International application No. PCT/JP2004/008355	International filing date ( <i>day/month/year</i> ) 15 June 2004 (15.06.2004)	Priority date ( <i>day/month/year</i> ) 27 June 2003 (27.06.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant EIKEN KAGAKU KABUSHIKI KAISHA		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).
  2. This REPORT consists of a total of 8 sheets, including this cover sheet.
- In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:
 

<input checked="" type="checkbox"/> Box No. I	Basis of the report
<input type="checkbox"/> Box No. II	Priority
<input checked="" type="checkbox"/> Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
<input type="checkbox"/> Box No. IV	Lack of unity of invention
<input checked="" type="checkbox"/> Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
<input checked="" type="checkbox"/> Box No. VI	Certain documents cited
<input type="checkbox"/> Box No. VII	Certain defects in the international application
<input checked="" type="checkbox"/> Box No. VIII	Certain observations on the international application
4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 24 April 2006 (24.04.2006)
Facsimile No. +41 22 740 14 35	Authorized officer <div style="text-align: center; font-weight: bold;">Masashi Honda</div> Telephone No. +41 22 338 70 10

# PATENT COOPERATION TREATY

TRANSLATION

From the  
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing  
(day/month/year)

Applicant's or agent's file reference

**WP-042**

**FOR FURTHER ACTION**

See paragraph 2 below

International application No.

**PCT/JP2004/008355**

International filing date (day/month/year)

**15.06.2004**

Priority date (day/month/year)

**27.06.2003**

International Patent Classification (IPC) or both national classification and IPC

Applicant

**EIKEN KAGAKU KABUSHIKI KAISHA**

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/008355

Box No. I

Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐

This opinion has been established on the basis of a translation from the original language into the following language

\_\_\_\_\_, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒

a sequence listing

☐

table(s) related to the sequence listing

b. format of material

☐

in written format

☒

in computer readable form

c. time of filing/furnishing

☐

contained in the international application as filed.

☒

filed together with the international application in computer readable form.

☐

furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 7

because:

☒ the said international application, or the said claims Nos. 7  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

The subject matter of claims 7 relates to a method for treatment of the human body.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_  
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 7

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
<b>1. Statement</b>			
Novelty (N)	Claims	1-6, 8	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-6, 8	NO
Industrial applicability (IA)	Claims		YES
	Claims	1-6, 8	NO
<b>2. Citations and explanations:</b>			
<p>Document 1: T, NOTOMI et al., Nucleic Acids Res. (2000), Vol.28, No.12, page e63(i-vii)</p> <p>Document 2: WO, 00-28082, A1 (Eiken Chemical Co., Ltd. ), 18 May, 2000 (18.05.00), &amp; EP 1020534 A1 &amp; US 6410278 B1</p> <p>Document 3: WO 02/24902 A1 (Eiken Chemical Co., Ltd.), 28 March, 2002 (28.03.02), &amp; EP 1327679 A1</p> <p>Document 4: C, DROSTEN et al., N. Engl. J. Med. May 2003 (05.03). Vol.348, No.20, pages 1967 to 1976</p> <p>Document 5: J, YANG, et. al., Di Yi Jun Yi Da Xue Xue Bao = Academic J. First Medical Collage of FLA, May 2003, Vol.23, No.5, pages 424 to 427, (abstract)</p> <p>Document 6: Eiken Chemical Co., Ltd. and Eiken Chemical stated co-research with Tropical Medical Laboratory, Nagasaki University on the development of SARS coronavirus detection reagent by use of LAMP process. 19 June 2003 (19.06.03)</p> <p>&lt;URL: <a href="http://mvw.tn.nagasaki-u.ac.jp/japanese/SARS_news_release.PDF">http://mvw.tn.nagasaki-u.ac.jp/japanese/SARS_news_release.PDF</a>&gt;</p> <p>Document 7: GenBank NC_004718.3, 23 June 2003 (23.06.03), M, A, MARRA, et. al., SARS coronavirus, complete genome,</p> <p>&lt;URL: <a href="http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?30271926:OLD12:897150">http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?30271926:OLD12:897150</a>&gt;</p> <p>Document 8: Fujitsu Ltd., provides dedicated primer design support service for PRESS RELEASE LAMP process via Website. The company also started the operation of e-market place for selling LAM products. 16 May 2002 (16.05.02)</p> <p>&lt;URL: <a href="http://pr.fujitsu.com/jp/news/2002/05/16-1.html">http://pr.fujitsu.com/jp/news/2002/05/16-1.html</a>&gt;</p> <p>[Claims: 1-6, 8]</p> <p>Subject matters of claims 1-6, 8 do not appear to involve an inventive step since they are described in documents 1-8 cited in the ISR.</p> <p>Document 1 to 3 notes the principle of LAMP (loop-mediated isothermal amplification) process, while document 1 teaches optimum conditions of LAMP process (see Optimized conditions for LAMP, page v).</p> <p>Document 4 describes the base sequence of polymerase gene segments (BNI-1) of SARS (severe acute respiratory syndrome) coronavirus, noting the method for detecting SARS coronavirus by PCR process targeting the base sequence. (See ESTABLISHMENT OF DIAGNOSTIC PCR ASSAYS TARGETING THE BNI- FRAGMENT, Fig. 1 B, page 1963). The sequence in which thymine (T) with the base sequence of BNI-1 is converted to uracil (U) described in document 4 has 100% homology with the base sequence of sequence No.1 of the invention of the present application.</p> <p>Document 5 describes a method for detecting SARS coronavirus by amplifying a segment of polymerase gene of SARS coronavirus (see Abstract).</p> <p>Document 6 describes that the development of reagent for detecting SARS using LAMP process has been started.</p> <p>Document 7 describes the complete genome consequence of SARS coronavirus including the</p>			

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Box No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

sequence in which uracil (U) of the base sequence is converted to thymine (T) stated in the sequence No.1 of the present invention.

Document 8 describes that they are going to provide "LAMP dedicated primer designing support software" which enables LAMP primer sequence designing, through Internet as a portal service of the portal site "NetLaboratory (<http://www.netlaboratory.com/>)".

A person skilled in the art could have easily conceived designing a primer by use of polymerase gene sequence noted in document 4 or 7, and detecting SARS coronavirus by means of the LAMP process noted in documents 1 to 4, in an effort to detect SARS coronavirus by LAMP process targeting RMA polymerase, taking into account the descriptions of documents 4-6.

The above consideration concludes that a person skilled in the art could have easily designed an optimum LAMP process primer, taking into consideration the optimum conditions of LAMP process noted in the document 1, or by use of [LAMP dedicated primer designing support software] noted in the document 8.

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Box No. VI Certain documents cited

1. Certain published documents (Rule 43bis.1 and 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
CN 1458281 A [EX]	26.11.2003	18.06.2003	

2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
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WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY

International application No.

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Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

The base sequence regions of "F3c", "F2c", "F1c", "R3", "R2" and "R1" described in the claim 3 are not clear, since only their relative positions are shown, and the base sequence region length and their absolute position are not disclosed in the specification.